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AGRICULTURAL BIOTECHNOLOGY - OPPORTUNITIES AND CHALLENGES

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November 1994
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AGRICULTURAL BIOTECHNOLOGY - OPPORTUNITIES AND CHALLENGES

AGRICULTURAL BIOTECHNOLOGY AT THE CROSSROADS

Ten years ago, the word biotechnology was used to signify a variety of activities and uses. A consensus has gradually developed whereby biotechnology is defined as a set of technologies, methods or tools but not a monolithic entity. Agriculture and Agri-Food Canada's formal definition sees biotechnology as "the applied use of living organisms, or their parts, to produce new products." Many traditional food-making processes depend on living organisms: yeast, a fungus, is used to make bread rise; bacteria are used to "age" cheese and make sour cream. Some medicines, such as antibiotics, are manufactured from substances produced from other organisms, such as bacteria and fungi. Today, scientists are refining these biotechnology methods so that the results are controlled and specific.(1)

Ten years ago, it was even questioned whether agricultural biotechnology would be part of the agri-food system. Today, when we are on the verge of having an impressive portfolio of available products, the emphasis has shifted to the benefits and risks of these biotechnology applications.(2)

It is still not clear what forces drive the biotechnology agenda. From the point of view of the public this is an important issue; unless there is public input into this agenda, technology will have free rein to develop in response to the profit motive rather than for solving particular food or health problems.

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(1) Agriculture Canada, *Biotechnology in Agriculture, Science for Better Living*, c. 1993, p. 1.

(2) National Agricultural Biotechnology Council, Report 3, *Agricultural Biotechnology at the Crossroads*, NABC, Ithaca, N.Y., 1991, p. 18 [hereafter NABC 3].

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Public concerns often centre on efficacy and health and environmental safety, but another criterion is now being debated - the socio-economic effect of the product or technology. Given that biotechnologies are often the tools used to achieve particular socio-economic goals, the public is increasingly exercising its right to shape the developments of technology to reflect these goals. This places an onus on scientists, regulators, and policy-makers to understand and evaluate not only biotechnology's implications for human safety, animal safety and environmental risk but also its socio-economic impacts. This criterion was applied in the decision-making for the European Common Market's ban on growth hormones in food products and the Canadian government's delay of the use of rbST (recombinant bovine somatotropin) in this country.

Questions about the government's ability to protect public health and safety and promote technologies that respond to socio-economic concerns have placed control processes squarely at the centre of discussion. How can we establish regulatory regimes capable of differentiating between synthetic products that imitate their natural counterparts so closely that they pose no threat and products requiring special scrutiny before approval? How can these regulatory procedures be designed to assess adequately the benefits and risks of new agricultural biotechnology products?(3)

The paper discusses the agricultural biotechnology products now on the horizon, considers their potential benefits and risks for the public, reviews the regulatory role and comments on biotechnology's implications for agriculture.

CURRENT AND NEXT GENERATION AGRICULTURAL BIOTECHNOLOGY PRODUCTS

A. Introduction

Most scientists working in agriculture tend to view advances in biotechnology as being on the continuum of the ongoing process of refining and perfecting agricultural practices.(4)

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(3) Institute for Science in Society Conference, "Food Biotechnology: A New Paradigm for Food, the Farm and the Public," *Bio/Technology*, Vol. 11, December 1993, p. 1584.

(4) NABC 3 (1991), p. 98.

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Evidence of this continuum abounds in Canada. Milk production per cow, for instance, has doubled in the last 40 years so that we are producing more milk with half the cows. The same kind of efficiencies are evident in the swine, beef and poultry industries.(5)

Technology has played an active role in these improvements in genetics, nutrition, disease prevention and pest control. Some of the technologies commercialized before 1980 and now taken for granted include selective breeding, vaccination, veterinary diagnostics and therapeutics, artificial insemination, and crossbreeding. Embryo transfer and regulation of reproductive cycles came into general use about 1980.(6)

While there are many promising applications of biotechnology in agriculture, biotechnology is neither a panacea for all ills nor a replacement for established tools. It merely provides an additional approach.(7) Changing animal nutrition, selective breeding, administering hormones or (eventually) gene transfer, for instance, all offer different means of producing leaner meats. The best route may be a combination of techniques, including those using biotechnology. Similarly, new plants can be produced through selective breeding and cell culture as well as by genetic engineering techniques for extending the range of new traits that may be introduced into a plant from other species.

While the more lucrative therapeutic or diagnostic applications of biotechnology led in sales in 1995, the agri-food sector contributed $1 billion of the total $3.2 billion spent on biotechnology products in Canada that year.(8)

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(5) Senate of Canada, Proceedings of the Standing Senate Committee on Agriculture and Forestry, Issue No. 4, 22 September 1994, p. 30-31.

(6) NABC 3 (1991), p. 99.

(7) United States, Congress, Office of Technology Assessment, *Biotechnology in a Global Economy*, Congress of the United States, Washington, D.C., 1991, p. 100.

(8) Industry Canada, *Biotechnology in Canada*, a presentation to the House of Commons Standing Committee on Environment and Sustainable Development, 16 May 1996, p. 4.

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B. Animals

Biotechnology applications to animals fall into four major categories: reproductive technologies, animal health care products, growth hormones and transgenic animals.

With respect to reproduction, biotechnology is able to refine procedures carried out by selective breeding for generations. Thus, traits from genetically superior female animals can be propagated using embryo transfer techniques and sperm can be separated to permit sex determination. In addition, bovine embryos can be stored in liquid nitrogen to allow more flexibility in their use, importation and exportation and certain laboratory techniques permit the embryos to be split into multiple identical copies.[9]

The application of biotechnology to animal health care products is similar to the application of the results of R and D to health products for humans, and often these products are developed by the same firms. Monoclonal antibodies have been developed into new diagnostic products for animal diseases like those used in tests for human disease. New, safer animal vaccines, including genetically engineered vaccines for such diseases as scours and rabies, have also been developed.

Recombinant bovine growth hormone or bovine somatotropin was approved by the U.S. Food and Drug Administration in 1994 as a stimulant to milk production. As one of the products of agricultural biotechnology most evident to the consumer and the producer, it has met with a mixed reaction. Concerns about its possible effects on animal and human welfare and on an industry already experiencing surpluses have led to moratoria on its use in the European Community, Canada, and various U.S. states such as Wisconsin, Minnesota and Vermont.

Use of animal growth hormones is also being studied as a way to produce leaner meats. Selective breeding has already resulted in leaner hogs and beef but the administration of genetically engineered growth hormones can have this effect and can also speed growth and improve feed efficiency.[10]

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(9) U.S. Congress (1991), p. 100.

(10) *Ibid.*, p. 102.

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As an alternative to farmers' use of growth hormones to treat animals, it is thought that growth hormone genes could be transferred directly into the genomes of animals. The ability to transfer sections of genetic code into the genome of an animal - thereby creating a new genetic resource for a species - is termed transgenic technology.[11] For this to come about, more knowledge about gene function as it relates to production traits in farm animals is required. This is an expensive technology involving species with long generation intervals[12] and food from transgenic livestock is not expected before the end of the century.

C. Plants

Modification of crop plants to improve their suitability for cultivation has gone on for at least 10,000 years.[13] Early farmers produced better crops by saving the seeds of desirable plants. During the past century, plant breeding has become more rigorous as a result of cross-breeding within a species and crossing sexually incompatible species of the same family. Now genetic engineering offers techniques for taking a gene from one species of plant and inserting it into a different species, something that would not occur naturally or through traditional breeding programs. Genetic engineering offers a means of endowing plants with new traits, thus expanding their repertoire of characteristics for withstanding insects, viruses, spoilage and herbicides.

Genetic engineers may also be able to fashion healthier foods from inserting into crops genes for proteins with superior nutritional properties. Plants could also be tailored to produce specific chemicals such as starches, industrial oils, enzymes and even pharmaceuticals. Preliminary trials on such innovations are underway.[14]

There are some technical problems with the transgenic science since genetic engineers can at present modify traits expressed by no more than three to five genes. Furthermore,

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(11) NABC 3 (1991), p. 38.

(12) *Ibid.*, p. 104.

(13) Charles S. Gasser and Robert T. Fraley, "Transgenic Crops," *Scientific American*, June 1992, p. 62.

(14) *Ibid.*, p. 69.

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some crops do not respond to current gene-transfer methods, and isolating useful genes for insertion is sometimes difficult.

There is no doubt that biotechnology offers tremendous potential for increasing food production if these technical problems can be overcome. It is estimated that food production will have to increase threefold during the next 40 years to meet the needs of an estimated nine billion people. Biotechnological breakthroughs could provide breathing space to deal with upcoming serious demographic problems and problems of environmental degradation and distribution of wealth.

According to the literature, the hundreds of field tests of engineered plants being conducted in the U.S. and Europe confirm their safety and potential commercial viability and the new crops should be available to farmers in the mid-1990s.[15] Nevertheless, in 1989 and 1990 groups in the Netherlands and Germany protested against such tests.

It would appear that non-technical, rather than technical, issues may delay commercialization of some technologies, even if they are approved by regulatory agencies.[16] Such issues are likely to be financial constraints and lack of public acceptance as a result of concerns about food safety and ethics, the environmental impact, and lack of understanding of the new technology. Thus, the next section of this paper looks at public perceptions of the benefits and risks of biotechnology.

PUBLIC PERCEPTIONS OF THE BENEFITS AND RISKS

The ability to improve plants, animals, and microorganisms in ways described above could mean dramatic improvements in the quantity and efficiency of food production and processing and the extension of uses of raw agricultural commodities. Consumers could benefit from reduced prices and safer and more nutritional foods. The new technologies also have the

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(15) *Ibid.*

(16) National Agricultural Biotechnology Council, Report 5, *Agricultural Biotechnology: A Public Conversation about Risk*, NABC, Ithaca, N.Y., 1993, p. 73.

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potential to change the very nature of food itself and to expand the range of possible food products. Consumers will show whether they find biotechnological food products acceptable by whether or not they buy them.[17]

Certain aspects of biotechnology raise questions regarding the ethics of tampering with the genetic material of animals and ultimately the balance of nature. Instances where the public has been assured that scientific breakthroughs - especially in the health sector - are safe, only to be told down the road of emerging health problems, have made the public cynical about the information provided by developers of innovative products on which even government in its regulatory role has to depend for information. The promotional material these companies provide is not as likely to address the likelihood of long-term safety or environmental problems.

Consumer surveys[18] conducted between 1992 and 1995 show that consumers have more faith in information provided by third party experts, such as national health and nutritional organizations, for weighing the pros and cons of biotechnology. Generally speaking, consumers see nothing wrong in using biotechnology to alter plants but feel it is morally wrong to use it to change animals. Consumers have indicated they want to be informed through labelling about foods that have been altered, and favour such foods that provide tangible health benefits (for instance less fat). In Canada, most consumers are reported to have a high degree of confidence in the federal government to regulate and assess these products for health and safety.

While a product is undergoing development, however, there is no mechanism in Canada or the U.S. for involving the public in the process. The U.S. approval process of recombinant bovine somatotropin (rbST) is a case in point. By the time field tests were approved, there was considerable public controversy about the efficacy of this drug which was designed to be given to cows to improve their milk production. The approval agency, the Food and Drug Administration, had to take the unusual steps of orchestrating a public hearing process and gaining the permission of the applicant companies to release the results of safety studies to the public domain.

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(17) *Ibid.*, p. 74.

(18) D'Arce McMillan, "Consumers Seen As Unfazed by Biotechnology," *The Western Producer*, 20 June 1996, p. 5.

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Likewise, in Canada there is no public review process to allow discussion of upcoming biotechnology decisions before they are approved. Nevertheless, Canada delayed the use of rbST for more than one year whereas the U.S. approved it in February 1994. Agriculture and Agri-Food Canada now publishes "decision documents" on its website on the Internet, "InforAgBiotech," explaining the regulatory decisions it has made in relation to novel plants. The site is intended to make the department's regulatory system more widely understood. The department also publishes regulatory guidelines as they are approved. As well as the decision documents for products that have been approved, the website includes information on regulations, guidelines, consultation documents, and lists of field trials. This certainly represents the beginning of a dialogue between the regulator and the public.

Another concern relates to the ownership of these technologies, many of which are in the commercial hands of multinationals that transcend geographic boundaries and hold limited national allegiance.[19] The patenting of plants and animals by these corporations has the potential to threaten genetic diversity, particularly in the Third World. In theory, the genetic engineering of plants can provide the latest technology to farmers in a very traditional package, the seed, to which even the most impoverished nations could have access without the need for high-technology supplies. In practice, however, biotechnology can make the seeds too expensive for poor farmers. Moreover, natural crops may be replaced by synthetic equivalents; for example, in Madagascar, 100,000 farmers are dependent on the vanilla crop, which is to be replaced by a cheaper bio-synthetic product. In such ways, those who provide the indigenous resource placed under patent end up unable to benefit from the technology.[20]

Another example closer to home arises out of the development of herbicide-resistant crops. Should these become increasingly concentrated in a few hands, as appears to be a trend, it must be asked whether farmers will be better off. Whose interests are being served by the promotion of such products?

It is important for everybody, including biotechnology developers, to make the public feel comfortable with biotechnology. Indeed, public acceptance and support has been identified as a key component in creating a viable competitive environment for biotechnology in Canada. Greater public participation would enable the biotechnology agenda to reflect more

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(19) NABC 3 (1991), p. 163.

(20) Sonya Dakers, *Biotechnology and the Public Good: NABC 6 Conference Report*, Mini-Review MR-127E, Research Branch, Library of Parliament, Ottawa, 28 June 1994, p. 2.

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accurately a society's diversity of values, interests and priorities and encourage consideration of environmental and social concerns. An acceptable biotechnology agenda must include participatory decision-making to ensure that applications of biotechnology serve the public good, as well as an accessible and consistent regulatory system to safeguard the quality of resulting food products.

It would appear to make sense for the developers of biotechnology to prepare the public for innovations by providing good information before they have made a significant investment in research and development. It would then be possible to gauge the reaction of the public to potential biotechnological products.

The public sector has historically played a role in conducting fundamental research relating to the biotechnology industry and should continue to do so, since companies may be unwilling to take on more high-risk research at this time of major spending reductions. If this does not continue, government will not be able to evaluate the efficacy of new technologies. This would be especially true where research related to the risk assessment of new organisms, monitoring their dispersal, or studying gene transfer or other areas where biosafety information might be incomplete. Unlike Canada, the U.S. Department of Agriculture has designated a specific percentage (1%) of its biotechnology research funding for risk assessment work.[21] This type of research is one means of addressing public concerns since it leads to better methods of controlling and monitoring new products of biotechnology.

The next section of this paper looks at how government here carries on regulatory functions to ensure that benefits and risks are adequately assessed and communicated to the public. A strong regulatory framework provides assurance that the products of biotechnology meet acceptable standards for the protection of human health and the environment and sends a signal of confidence to the domestic and international market.[22]

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(21) NABC 3 (1991), p. 141.

(22) Agriculture Canada, *Workshop on Food Biotechnology*, Proceedings, Ottawa, 29 March 1993, p. 4.

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REGULATION AND RISK ASSESSMENT

Federal activity in biotechnology began in 1980 when a private sector task force was commissioned to advise the government on this new science. In its report, the task force recommended establishing a national strategy that would encourage a strong and competitive Canadian industry.

In response, the federal government in 1983 established the National Biotechnology Strategy Program; initially, it was to run for five years, but it was extended and will now end in 1997. The program consisted of an industry-government National Biotechnology Advisory Committee (NBAC) to advise the Minister of Industry on new policy requirements; multi-disciplinary centres of excellence to encourage technology transfer; seven sectoral networks to promote scientific cooperation in priority research areas; and an Interdepartmental Committee on Biotechnology (ICB) to coordinate federal biotechnology policy.

In 1987, the NBAC published eight key criteria intended "to develop a regulatory system able to determine whether the commercial benefits from the substantial investments made to date would be reaped in Canada."[23] The regulatory task was to: engender public confidence; make economic sense; allow industry planning for development and commercialization; be compatible with international approaches; be flexible and accommodate new approaches; clarify jurisdictional approaches; and draw on independent scientific advice.

Departments having regulatory responsibilities, such as Agriculture and Agri-Food Canada, began to draft regulatory proposals under their specific mandates. Together, as part of the Interdepartmental Subgroup on Safety and Regulations, in 1988 they drafted *Bio-tech Regulations: A User's Guide*. That same year, the departments of Agriculture, Environment, Health, Labour and Fisheries were directed by Cabinet to develop a plan of action for a coordinated regulatory system for the products of biotechnology. In 1990, the Green Plan set a five-year framework for implementation. It also called for national standards and codes of practice for protecting the

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(23) *Ibid.*, p. 4.

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environment and human health following accidental or deliberate release of products. The Green Plan also called for notification of new biotechnology products prior to release or introduction.(24)

The basic principles of *The Federal Framework for Regulating Biotechnology Products* were announced on 11 January 1993. They included using existing legislation and regulatory institutions to clarify responsibilities and avoid duplication; developing guidelines for evaluating products of biotechnology that uphold domestic health and environmental safety standards; using risk-based assessments and supporting a consultative regulatory process.(25)

In 1993, the ICB proposed that the departments adopt a series of definitions to ensure consistency with respect to references to biotechnology in all federal documents and communications. They included definitions for "product" versus "process" regulation, risk-based assessment and a single-window approach and adopted the *Canadian Environmental Protection Act*'s definition of biotechnology as: "...the application of science and engineering in the direct or indirect use of living organisms or parts or products of living organisms in their natural or modified form" (CEPA, Section 3(1)).(26)

In agriculture, this definition includes genetic engineering and novel technologies of molecular biology such as tissue culture, recombinant DNA and mutagenesis. Agriculture and Agri-food Canada, as agreed in the federal framework for biotechnology, regulates on a "commodity," or "product," basis. The department regulates new products of biotechnology in the same way as traditional products under various agricultural statutes and commodity areas, based on the requirement that they be safe and efficacious regardless of how they were developed.(27) On 11 January 1995, regulations under these Acts were amended to clarify that they covered biotechnology products.

New varieties of plants and forestry trees, including plants with novel traits, are regulated under the *Seeds Act*. This includes "transgenic plants," new crop varieties that are

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(24) Agriculture and Agri-Food Canada, *Workshop on Regulating Agricultural Products of Biotechnology*, Proceedings, Ottawa, 8-10 November 1993, p. 4.

(25) *Ibid.*

(26) *Ibid.*, p. 6.

(27) The following description of the agricultural legislation is taken from Thomas Curran, *Briefing Notes on Biotechnology*, 12 June 1996, p. 4-6 and Agriculture and Agri-Food Canada, Biotechnology Presentation to the House of Commons Standing Committee on Environment and Sustainable Development, 16 May 1996, p. 3-4.

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created using "genetic engineering" or recombinant-DNA technology, as well as plants with novel traits developed using older technologies, including mutagenesis and traditional cross-breeding. The introduced genes may confer such traits as improved protein content, tolerance to a herbicide, resistance to frost damage, or resistance to insects. Assessments of plants with new traits are conducted regardless of the breeding method or process used to develop them. Approvals for field testing and commercialization take place only after thorough environmental assessments have been performed.

While Agriculture and Agri-Food Canada is responsible for the agronomic and ecological safety assessments of crops, in the case of food crops, Health Canada is the department with primary responsibility for matters of food safety. To cite an example, Health Canada conducted an assessment of the **New Leaf** potato - genetically modified to protect against Colorado potato beetle infestation - to determine the safety of the product and its acceptability for food use.

Feeds are regulated under the *Feeds Act*. A feed is defined as "any substance or mixture of substances manufactured, sold or represented for use for consumption by livestock, for providing the nutritional requirements of livestock, or for the purpose of preventing or correcting nutritional disorders of livestock." In addition to traditional types of feeds, there are also "biofeeds," which may include microbial products (both living and non-living), plants with novel traits (see above), and a variety of fermentation products such as enzymes, biomass proteins, amino acids, vitamins and flavouring agents. Assessments focus on toxicity to livestock, anti-nutritional and allergenicity effects, and human safety.

Veterinary biologics are regulated under the *Health of Animals Act*. This category includes a variety of products, including animal vaccines, toxins, bacterins,[28] toxoids,[29] antisera, and diagnostic kits used for the diagnosis, treatment, mitigation or prevention of infectious diseases of animals. The majority approved so far have been diagnostic kits, such as those used to detect animal diseases. Other products regulated under the *Health of Animals Act* include animal pathogens, animal products and by-products, and transgenic animals with disease-resistance claims.

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(28) A "bacterin" is a suspension of killed or attenuated bacteria for use as an antigen.

(29) A "toxoid" is a toxin of a pathogenic organism treated so as to destroy its toxicity but still leave it capable of inducing the formation of antibodies on injection.

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Fertilizers are regulated under the *Fertilizers Act*. These products are developed to supply plants with nutrients, and can include microorganisms. Microbial fertilizers have been used as alternatives to chemical-based products for many years, particularly as seed coatings. For example, seed coating microorganisms produce fertilizer naturally. The safety assessment focuses on identifying the organism and its behaviour in the environment in terms of any adverse health effects.

Importation of plants, microorganisms and animals is controlled by import permits under the *Health of Animals* and *Plant Protection Acts*. Import permit reviews examine the potential of a new imported plant, animal or microorganism for having adverse effects on human safety, animal safety and ecological impact.

Finally, the *Canadian Agricultural Products Act* provides authority for the safety and integrity of agri-food products through standards and mechanisms such as certification and inspection.(30)

This means that new agricultural products, like conventionally derived products, are regulated according to product characteristics. The criteria of "familiarity" and "substantial equivalence" are used to determine whether risk should be assessed; risk assessments estimate the hazard to human beings or the environment; and safety and performance standards are applied. This procedure applies to imports, field research, and the pre- and commercialization stages of a product.(31)

In developing guidelines in the various commodity areas outlined above, the department has held consultations and workshops to receive input on the acceptability of its approaches to biotechnology. A number of issues have arisen, one of which concerns the criteria for determining which products need to undergo risk assessment. There has also been a realization that "familiarity" depends on the existence of a broad body of information, including information on the safety of any product considered to be a substantial equivalent to the new product of biotechnology. In the proposed model, the degree to which a product/use is "familiar" and "substantially equivalent" to an accepted one will determine which new products require an assessment of potential risk. The risk assessment process itself, which is not new, identifies potential hazard, and determines exposure and risk.

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(30) Agriculture Canada, *Workshop* (1993), p. 6.

(31) *Ibid.*, p. 6-7.

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For the proposed model to function usefully, the knowledge bases used in determining both "familiarity" and "substantial equivalence" must be capable of evolving. How this works can be seen in the case of canola, originally assessed for the safety of oil and feed meal products. The broad experience we have had since then with canola cannot be considered sufficient to deem a new canola variety (for instance, developed through recombinant DNA to produce a specialty vegetable oil) "substantially equivalent" though we do have sufficient "familiarity."[32]

Some of the other issues arising in the context of the new policy are: the impact of regulation on competitiveness, its transparency, its flexibility, its credibility, the need for monitoring its effectiveness, and the need for public participation in the process.

These are not issues that are easily resolved equitably. To compete, Canada needs a well-defined and predictable regulatory framework on which to make business and investment decisions. At the same time, to gain credibility in the public's eyes, the regulatory framework also needs to be sensitive to issues of public acceptability. This is a delicate balance to maintain.

On the international scene, Canada's approach falls midway between stringent biotechnology-specific regulation and no regulation. The U.S. is following a similar route and is also relying on the existing legislation under which it has already approved many new products. The USDA (U.S. Department of Agriculture) and EPA (Environmental Protection Agency) have already established procedures for reviewing field tests of modified plants and micro-organisms.[33] The EU (European Union) has taken a more stringent approach; it has enacted directives that are specific to biotechnology-derived products and is considering adding socio-economic assessments of new products.

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(32) *Ibid.*, p. 12.

(33) U.S. Congress (1991), p. 196.

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TYING IT ALL TOGETHER

Despite their potential for improving and expanding global food supplies, developments in food biotechnology are emerging in a climate of public uncertainty. The controversial reaction to the use of synthetic bST illustrates the limited public understanding of products of biotechnology and their benefits and risks.

Some see technological innovation in agriculture as ever-evolving, with biotechnology merely the latest chapter. For them, biotechnology has the potential to increase crop yields, renew the vigour of plant and animal genetics, encourage species conservation (by making genes from native plant species more available and valuable), encourage biodiversity, reduce the need for farm chemicals, and help increase Third World affluence, thereby slowing population growth.(34)

For others, biotechnology requires special vigilance and treatment that is qualitatively different. They do not believe that the ultimate direction of biotechnology is necessarily toward a more humane, egalitarian, socially just, and ecologically sound agriculture, despite the opportunities for increasing crop diversity, yields, and Third World affluence. They see the opposite: huge amounts of resources are at present being spent on developing herbicide-resistant varieties of crops of which we already have large surpluses and on increasing milk productivity when milk is currently over-produced. Moreover, Third World farmers are not always benefiting from supplying the life forms/seeds placed under patent and said to encourage bio-diversity. These observers see economic considerations as the driving force behind biotechnological developments carried on without any consideration of broad ethical and environmental concerns.

Between these two quite divergent viewpoints are others. Parliamentary hearings held during 1996 revealed wide differences of opinion on the notification and regulation of biotechnology products, particularly those that are created by recombinant-DNA technology.

The environmental community favours an approach more like the EC's, with regulation under new legislation specifically drafted for biotechnology or consolidated under the

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(34) *Bio/Technology* (1993), p. 1585-88.

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Canada Environmental Protection Act (CEPA). Currently, CEPA regulates only those biotechnological products not regulated under other federal statutes, leaving primary responsibility to line departments having the traditional expertise and experience in relation to specific classes of products.(35) In its present form, CEPA does nevertheless give Environment Canada the legislative authority to set minimum standards for notice and assessment of **all** products of biotechnology, both living and inanimate [section 26 (3) (a)].

In conformity with its 1993 *Federal Framework for Regulating Biotechnology Products*, the government proposes using CEPA as a "safety net" for those areas not covered by other federal Acts.(36) The government did agree to create a new Part of CEPA to deal specifically with living products of biotechnology not covered by other Acts that would require notification of data and product assessment for long-term human and environmental effects. The proposed safety net approach, however, would confine Environment Canada's standards for notice and assessment to new products not covered by existing legislation. CEPA would no longer be the basis for setting minimum standards.

An open public discussion of biotechnology's role in agriculture is still needed, based on balanced and credible information. The capacity of biotechnology to be a useful tool in dealing with major problems such as the environment, hunger and population growth must be part of the public debate. Any health, safety, ethical, economic or other concerns of the public must be openly addressed in both regulatory and educational forums.

In Canada, there is a certain reliance on the government's ability to protect the public's health and safety; however, mechanisms whereby the public can indicate concerns or pose questions must be provided if the government is to maintain this credibility. Because consumers are concerned about the content of the food they buy, labelling genetically engineered foods will be important, as will knowledge about the effect of long-term exposure to them. The future of genetically engineered foods will depend on consumers' confidence in them and their benefits.

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(35) Canada, Parliament, House of Commons Standing Committee on Environment and Sustainable Development, *It's About Our Health: Towards Pollution Prevention*, June 1995, p. 123.

(36) Environment Canada, *Environmental Protection Legislation Designed fort the Future - A Renewed CEPA*, Minister of Supply and Services, Ottawa, 1995, p. 51.

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To some extent, the scientific community bears the burden of demonstrating to the public that biotechnology products are both desirable and safe. Most people have very strong emotional, cultural, and religious feelings about food. Some believe that tinkering with animal or plant genes violates the integrity of the species. It would behove the developers of biotechnology to be judicious in their selection of the early genetically engineered foods that come to market in order to ensure that the benefits outweigh the risks. The experience with rbST shows that a public dissatisfied with the efficacy of a product will strive to make itself heard and, lacking any other forum, will turn to the media to make its point. This is not necessarily the best mechanism for public debate of biotechnology and its benefits and risks.[37]

(37) *Ibid.*, p. 1588.